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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,601	09/24/2003	Aviv Shaish	25727	1529

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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	PAPER NUMBER
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/668,601	SHAISH ET AL.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *2 and 11-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-10 and 28* is/are rejected.

7)☒ Claim(s) *29 and 30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on October 10, 2006. Further acknowledgment is made of newly added Claims 28-30; and, the Declaration under 37 C.F.R. § 1.131 filed by the present inventors, Avish Shaish and Dror Harats.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

This application contains Claims 11-27 drawn to an invention nonelected without traverse on March 6, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 3-10 and 28-30 are under examination.

Response to Arguments

The rejection of Claims 1, 8 and 9 under 35 USC 102(b) as being anticipated by Hayashi et al. (N) made in the previous Office action has been removed, in view of Applicants' persuasive arguments, and the persuasive arguments made in the Declaration under 37 C.F.R. § 1.131 filed by the Shaish et al. Along with the accompanying documentation (Exhibits A through D) that provide supporting evidence that Applicant's date of invention occurred prior to the July 2, 2003 effective date of the

Hayashi' reference. Accordingly, the rejections of Claims 1-3 and 8-10 under 35 USC 103(a) have been overcome by Applicants' persuasive arguments; and, thereby removed herein.

Claim Rejections - 35 USC § 103

Claims 1, 8 and 28, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Kesharlal et al. (P) in light of evidence readily admitted by Applicant. Newly applied as necessitated by amendment.

Applicant claims a method for reducing insulin and/or glucose plasma levels in a subject afflicted with diabetes comprising administering to the subject an effective amount of dried Dunaliella alga, thereby reducing the subject's plasma insulin and/or glucose plasma levels. Applicant further claims the dried Dunaliella algae are administered orally. Applicant further claims the method according to claim 1, wherein the dried Dunaliella algae comprise β-carotene.

Kesharlal teaches a composition comprising carotenoids obtained from Dunaliella salina, which is used in a method of treating diabetes. As readily disclosed by Applicant on page 1 of the present specification, lines 24-26, Dunaliella salina contains large amounts of β-carotene. Therefore, absent evidence to the contrary, the anti-diabetic composition taught by Kesharlal is deemed to inherently comprise β-carotene. (*See* the teachings of Tanaka in US 4,915,965, as well.)

The teachings of Kesharlal are set forth above. Kesharlal teaches the instantly claimed invention except for wherein the composition is administered to provide a

method for reducing glucose levels in an individual afflicted with diabetes. However, it would have been obvious to one of ordinary skill in the art to administer the composition taught by Kesharlal to provide the instantly claimed invention because at the time the invention was made it was well known in the art of medicine that anti-diabetic agents generally had the functional effect to reduce glucose levels in an individual afflicted with diabetes. Thus, at the time the invention was made one of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success to administer the composition taught by Kesharlal to provide the instantly claimed invention because at the time the invention was made Kesharlal taught that that the referenced composition in the form of a tablet (read herein as dried Dunaliella algae) comprising an extract of Dunaliella was effective in the treatment of individuals afflicted with diabetes.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1, 8, 10 and 28, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Kesharlal et al. (P) in view of Takenaka et al. (N) and Tanaka et al. (D*). Newly applied as necessitated by amendment.

Applicant's claimed invention of Claims 1, 8 and 28 was set forth above. Applicant further claims the method according to claim 1, wherein the dried Dunaliella alga is encapsulated.

The obvious teachings of Kesharlal are set forth above. Kesharlal teaches the instantly claimed invention except for wherein the dried Dunaliella alga is encapsulated. However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method taught by Kesharlal by encapsulating the referenced composition to provide the instantly claimed method because it was known in the art that the encapsulation of dried Dunaliella algae was useful as a vehicle for the delivery of the claim-designated ingredient to patients in need thereof of therapeutic treatment requiring the oral administration of Dunaliella powder, as evidenced by the teachings of Takenaka and Tanaka. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to modify the form of the composition used in the obvious method of treatment taught by Kesharlal by encapsulating the Dunaliella algae instead of tableting the composition to provide the instantly claimed invention because Takenaka taught that the encapsulation of dried Dunaliella algae protects the unstable nutrient from decomposition by light and from degeneration by oxidation, and; Tanaka taught the encapsulation of dried Dunaliella algae comprising provides a convenient vehicle for oral administration of the claim-designated ingredient to patients in need of therapeutic regimens requiring dose amounts of β-carotene. Thus, the claimed invention would have been merely a matter of judicial selection to one practicing the invention the invention to pick and choose the form for the oral administration of the referenced algal composition to effect a result effect variable for the treatment of diabetes, since at the time the invention was made Kesharlal taught that the oral

administration of effective amounts of Dunaliella algae was useful in the treatment of diabetes, and given that Takenaka and Tanaka taught that the oral administration of the claim-designated algal composition in an encapsulated form was conventional and well known in the art.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1,3- 8, 10 and 28, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Kesharlal et al. (P), Takenaka et al. (N) and Tanaka et al. (D*) in view Beck (A*), Pan et al. (B*), Heyman et al. (C*) and Smith (O). Newly applied as necessitated by amendment.

Applicant's claimed invention of Claims 1, 8, 10 and 28 was set forth above. Applicant further claims a method according to claim 1, wherein said crude *Dunaliella* powder is administered together with one or more activators of nuclear receptors. Applicant further claims the method of claim 3, wherein the activators of nuclear receptors are peroxisome proliferator-activated receptor α or γ (PPARα or PPARγ) agonists. Applicant further claims the method according to claim 4, wherein the PPARα or PPARγ agonists are selected from fibrates and thiazolidinediones. Applicant further claims the method according to Claim 5, wherein the fibrates are selected from clofibrate, fenofibrate, bezafibrate, ciprofibrate, beclofibrate and gemfibrozil. Applicant further claims the method according to Claim 5, wherein the thiazolidinediones are

selected from AVANDIA™, troglitazone, BRL 49653, pioglitazone, ciglitazone, WAY-120,744, englitazone, AD 5075, darglitazone and rosiglitazone.

The combined teachings of Kesharlal, Takenaka, and Tanaka are set forth above. The combined teachings of Kesharlal, Takenaka, and Tanaka teach the instantly claimed invention except for wherein the crude Dunaliella powder is administered together with one or more activators of nuclear receptors. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredients to the method taught by the combined teachings of Kesharlal, Takenaka, and Tanaka to provide the instantly claimed invention because at the time the invention was made the instantly claimed activators of nuclear receptors were known in the art for their beneficial functional effect for treating diabetes, as evidenced by the teachings of Beck, Pan, Heyman and Smith. Firstly, Beck teaches a method for the treatment of normolipidaemic diabetes mellitus comprising orally administering an effective amount of bezafibrate. Secondly, Pan teaches a method of reducing the risk of or treating diabetes mellitus comprising administering an effective amount of an antihyperlipoproteinemic agent, *e.g.*, fenofibrate, gemfibrozil, clofibrate, bezafibrate, ciprofibrate and clinofibrate in combination with a cholesterol lowering drug, ACE inhibitor, in Column 9, lines 32-58. For example, in Column 15, line 58 to Column 16, line 2, Pan teaches administering gemfibrozil capsules either alone in combination with a cholesterol lowering drug, ACE inhibitor in the treatment of diabetes mellitus. Thirdly, Heyman teaches a method of treating diabetes mellitus comprising administering an effective amount of a thiazolidinedione, *e.g.,* troglitazone, BRL 49653 , pioglitazone,

ciglitazone, WAY-120,744, englitazone, AD 5075, and darglitazone, in combination with an RXR agonist to a subject. Fourthly, Smith teaches a method of treating diabetes mellitus comprising administering rosiglitazone. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the ingredients taught by Beck, Pan, Heyman and Smith to the method of treatment taught by the combined, obvious teachings of Kesharlal, Takenaka, and Tanaka to provide the instantly claimed invention because Beck teaches that the oral administration of bezafibrate reduces the insulin level in normolipidaemic patients suffering from diabetes mellitus; Pan teaches that his method reduces or prevents the onset of diabetes mellitus and the onset of atherosclerosis in mammals, in Column 4, lines 27-34; and, in Column, 2, lines 5-11, Heyman teaches that the combination of an RXR agonist and a PPARγ agonist, *i.e.,* a thiazolidinedione, achieves synergistic action of the RXR/ PPARγ heterodimers so as to enhance adipogenic and antidiabetic effects of PPARγ; and, Smith teaches that his method for treating diabetes mellitus comprising administering rosiglitazone provides a beneficial effect on glycaemic control, on page 1, lines 19-22.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed method because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the

prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Thus, at the time the invention was one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add any of the claimed ingredients taught by either Beck, Pan, Heyman or Smith to the encapsulated Dunaliella used in the method taught by the combined teachings of Kesharlal, Takenaka, and Tanaka to provide the claimed method because the claimed invention is no more than the combining of well known ingredients used in well known methods for treating diabetes in a subject in need thereof.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Allowable Subject Matter

Claims 9, 29 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claims are allowed.

It is noted that the term "Dunaliella" or "Dunalilla bardawil" are not italicized in the claims. Please italicize the terms to place them in proper grammatical form.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood

MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
January 8, 2007